Preventive mechanism for exploitation of the poor for clinical trials

1168. SHRIMATI BRINDA KARAT : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what regulatory mechanism Government have set up to prevent the exploitation of poor people who voluntarily go for clinical trials;

(b) in the context of many of the volunteers being uneducated persons, what are the guarantees that principle of informed consent is being followed; and

(c) in view of the dangers, whether Government are thinking of canceling the January, 2005 amendment to Schedule "Y" of the Drugs and Cosmetics Act?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) Detailed norms for conducting clinical trials on a new drug in the country are prescribed under Drugs & Cosmetics Rules 122-DA-122-E and also under Schedule Y to these rules. The clinical trial shall be initiated only after the permission from DCG(I) and approval from respective Ethics Committee is obtained.

Schedule-Y prescribes the requirements for permission to conduct clinical trials and/or manufacture or import of New Drugs for marketing in India. It also lays down safety and ethical aspects, responsibilities of sponsors, investigators and Institutional Ethics Committee etc. Modalities for obtaining informed consent from trial subjects, and a specific form for the same have also been prescribed. During and following a subject's Participation in a trial, the investigator has to ensure that adequate medical care is provided to participant for any adverse event.

The Government has brought out detailed guidelines on Good Clinical Practices and Indian Council of Medical Research (ICMR) had published Ethical Guidelines for Biomedical Research on Human Subjects, which are required to be followed during conduct of a trial.

These norms prescribed in India, are at par with international practices including that of U.S.A. Thus at present there is no requirement for canceling of the January 2005 amendment to Schedule-Y of Drugs & Cosmetics Act.